Preliminary Report: Neonatal Transport Unit

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BME 300/200

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Abstract

Neonatal transport puts extreme stress on neonates, who are often in critical condition, lowering their chance of survival [1]. Vibrational forces experienced by neonates during transport are linked to an increase in the odds of severe brain injury. In particular, intraventricular hemorrhaging (IVH), can lead to neurodevelopmental impairment or death [2], [3]. To resolve this issue, a metal and gel composite damper has been proposed to help mitigate the harsh vibrations. The damper consists of four concentric layers: silicone gel, aluminum, foam, and stainless steel. The device would have a ball and socket joint that would attach between the inner and outer tray of the incubator. This design is inspired by the anatomy of a woodpecker, which can naturally reduce vibrations. In conjunction with the damper, two additional components have been proposed: a head restraint to lessen whole body vibration by directly stabilizing the neonate, and a shock-absorbing mat to reduce the magnitude of the vibrational force exerted on the isolette bed [4]. The head restraint consists of a strap across the forehead with lateral supports on each side of the head, and a strap across the torso. The head restraint system has proved safer and more effective in reducing vibrations than the current five-point restraint system.

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I. Introduction

Motivation

The quality of transport for critically-ill neonates to a Neonatal Intensive Care Unit (NICU) directly influences chances of survival or morbidity [5]. The critically-ill neonate is often the result of a preterm birth (< 37 complete weeks of gestation) or underlying birth defects [6]. One in 10 babies need access to a NICU in the first week of life [7]. 1.3% of neonates are born *ex-utero* and must be transported to a NICU via ambulance or helicopter [8]. The current methods of transport expose a neonate to whole-body vibrations (WBV), translational and rotational motion, and excessive sound [9]. The effects of *ex-utero* transfer are well-documented in studies which conclude that transportation of a neonate significantly increases the odds of severe brain injury (odds ratio of 2.32) and significantly lower odds of survival without brain injury (odds ratio of 0.60) [2, 3]. One brain injury of concern is intraventricular hemorrhaging (IVH), which is closely associated with neonatal transport and can lead to subsequent neurodevelopmental impairment or death [10]. Therefore, reducing vibrations, mechanical forces, and excessive sound has the potential to significantly improve the outcomes of neonatal transport. There is no standardized vibration-reducing device used in neonatal transport, reflecting the need for a device that minimizes the environmental stressors transferred through the transport vehicle.

Existing Devices and Current Methods

The current methods of minimizing vibrations and mechanical forces by the UW Hospitals' neonatal transport teams involve the use of a Geo-Matrix mattress, a five-point harness, various pillows, and suspension systems. The mattress used in the incubator is derived from a simple gel mattress and is placed directly under the neonate during transport. The five-point harness secures the neonate in place using straps across the shoulders, hips, and thighs [11]. The transport team uses additional pillows and blankets to their discretion to manipulate the position of the neonate or support the head. Finally, the vehicle's suspension system, as well as the built-in suspension system on the gurney act to reduce forces transmitted through the ground.

These methods are insufficient in reducing vibrations and mechanical forces felt by the neonate, as whole-body vibration levels often exceed the recommended 0.87 m/s^2 in adults [9]. No standards have been developed for the recommended maximum vibration levels for neonates, but it can be reasonably assumed it is significantly less than the level for fully-developed adults. The current method does very little to mitigate vibrations and features many rigid parts directly in contact with one another.

The current method for minimizing excessive sound is using a pair of ear muffs. These muffs work exactly like regular ear muffs and are placed over the neonate's ears during transport. While effective at minimizing sound, the ear muffs used are easily displaced by movement of the vehicle or neonate. Thus, this is an ineffective method for mitigating excessive sound levels as the medical transport team does not have easy access to constantly adjust the ear muffs.

While no vibration-reducing device has been established as a standard for neonatal transport, several products have been created for this purpose. The first is the Quasi-Zero-Stiffness (QZS) Isolator which identifies and targets low-frequency components as the primary disturbing vibration [12]. This product modifies the incubator control box directly below the incubator itself by adding four QZS Isolators in each corner of the housing. Each QZS Isolator has a pair of repelling ring permanent magnets that are connected in parallel to a coil spring. The inner ring magnet is fixed to a central rod while the outer ring magnet is fixed on the sleeve that surrounds the rod. This concentric system of ring magnets mitigates the effects of rotational and translational motion and keeps the isolators aligned vertically, allowing the coil spring to take on most of the weight. Finally, a viscous damper is added inside the coil spring to help reduce vibrations and forces in the vertical direction. Although the concept of QZS Isolators is well supported, the design involves substantial alterations to the current transport setup, has a complicated design, and lacks experimental testing to verify its ability to reduce whole body vibrations.

A second design referred to as an isolation device for shock reduction occupies the space between the isolette (i.e. incubator) and stretcher platform [13]. The design features pairs of metal plates that serve as attachment points for gas or air springs. One plate is mounted to the top of the gurney while the other plate is mounted to the bottom of the isolette. Air or gas springs are fixed between the plates in order to provide dampening effects for the isolette. The pressure within the air springs can be adjusted to attenuate high or low frequencies of vibration. The

design specifies that two air springs are placed in each corner and one is placed in the center. A patent has been applied for relating to the use of parallel plates and air springs to reduce the transmission of kinetic energy between an isolette and support table (Application Number 11/540743). Similarly to the QZS Isolators, this design involves large modifications to the current transport setup. Additionally, it neglects the presence of the monitoring systems and associated housing which are located directly below the isolette.

Problem Statement

Whole-body vibrations, translational forces, rotational moments, and excessive sound from a medical transport vehicle can cause brain injuries to critically-ill neonates that lead to neurodevelopmental impairment or death. Mitigating these physiological stressors has the potential to drastically improve transport outcomes including increased survival rates and decreased brain injury. The current transport setup neglects the effects of the stressors aforementioned by including a collection of rigid parts with only a single mattress to dampen vibrations. Thus, the client has tasked the team with developing a vibration-reducing device with mitigating mechanical forces and sound as secondary foci. The device must reduce each physiological stressor so the neonate does not sustain injury, must fit within the confines of a standard ambulance and helicopter without interfering with the movement of the transport team, and must be compatible with current incubator setup or include all the associated functions (Appendix A).

II. **Background**

Relevant Physiology and Biology

The neonate brain is highly susceptible to injury due to its underdeveloped nature and lack of structural support systems. A neonate's brain is very soft (often compared to unset gelatin) and as a result very vulnerable [14]. Within the brain, neuronal-glial precursor cells make up a vascularized region called the germinal matrix [15]. This region is particularly vulnerable for infants due to weaknesses in the blood-brain barrier in the first 48 hours of life. Moreover, premature infants struggle with cerebral autoregulation which is the ability of cerebral

vessels to keep constant cerebral blood flow (CBF) regardless of changes in arterial blood pressure. The smooth muscle cells and pericytes responsible for minimizing variations of CBF are not fully developed. A fluctuating CBF is associated with pressure passivity in regards to cerebral circulation. Additionally, the neonate's central nervous system is at a very immature stage and is constantly undergoing organizational changes [9]. These changes, combined with physiological instability, limit a neonate's ability to coordinate autonomic and self-regulatory responses towards environmental stressors.

The fragility of a neonate brain described above increases susceptibility to intraventricular hemorrhage (IVH). Whole body vibrations can trigger IVH through a cumulative process beginning with cerebral vasoconstriction, increased free radicals, decreased nitric oxide, decreased cerebral blood flow, and repeated reperfusion injury [9]. These characteristics describe the progression of germinal matrix hemorrhage [15]. Furthermore, it is found that fluctuating cerebral blood flow velocity, commonly found in premature neonates, leads to higher chances of IVH. The nature of ground or air transport in conjunction with the neonate's unstable condition reveals the susceptibility of neonates to brain injury.

Relevant Design Information

The prospective design must function in conjunction with a preexisting setup. Understanding the organization of the transport setup is crucial to understanding design ideas and constraints. Descriptions of the setup are based on observations made from the transport incubator at UW Health, which is International Biomedical's Voyager model [16]. Regardless of the model, all transport incubators follow the same general structure. The setup includes an incubator (also known as an isolette) which encloses the neonate during transport. A removeable, inner tray supports a mattress and fixes on to a permanent, outer tray on the bottom of the incubator. Below the incubator is metal housing for the incubator's control systems in order to alter the environment of the incubator (e.g. temperature). This housing, with the incubator latched on top of it, is latched to a transport platform (also known as the deck). Also attached to the deck are a variety of support systems (e.g. oxygen tanks). The deck is then secured onto the gurney for transport.

Client Information

Dr. Ryan McAdams is the Neonatology Division Chief for UW Health and a professor for the UW School of Medicine and Public Health. Dr. Joshua Gollub is a fellow at the University of Wisconsin School of Medicine and Public Health specializing in neonatal medicine.

Design Specifications

The client has tasked the team with developing a novel transport bed to reduce physical stressors to a neonate during transport in an ambulance. The client requires that the device satisfies several identified problems which guided the requirements for the project as elaborated in the Product Design Specifications (Appendix A). The device must minimize vibrational forces below 0.87 m/s^2 for the entire duration of the transport [9]. The device must mitigate the effects of translational and rotational motion so that the neonate does not sustain injury. A sound-reducing feature must be added to the novel bed to reduce sound levels below the maximum accepted level of 45 dB [17]. The device must attach to the current incubators or include all the associated functions. Finally, the device must fit within the confines of a standard ambulance while allowing efficient movement of the transport team. Due to the constant nature of vibrations and motion during transport, the design should provide continuous functionality without disrupting the support systems and monitoring equipment. In terms of ergonomics, the device should be relatively easy to install and remove and require no additional manipulation once installed. The goal is to create a pilot model (i.e. functional prototype) that can be tested in mock ambulance transports and potentially be implemented as part of the standard transport equipment.

III. Preliminary Designs

The team brainstormed several ideas and creative solutions to address the problem of reducing whole body vibrations to provide neonates with an improved chance of survival. The team decided on three designs to be formally illustrated and evaluated, each with distinct properties and ways to reduce vibrations.

Magnet-Induced Levitation Device

The first of these designs utilize the repulsion force created by magnets when two ends of the same polarity are in too close proximity. The goal of this device is to create a combination of attractive and repulsive force beneath the incubator that will act as a cushion and absorb any vibrations encountered during transport. As such, it was named the Magnet-Induced Levitation Device.

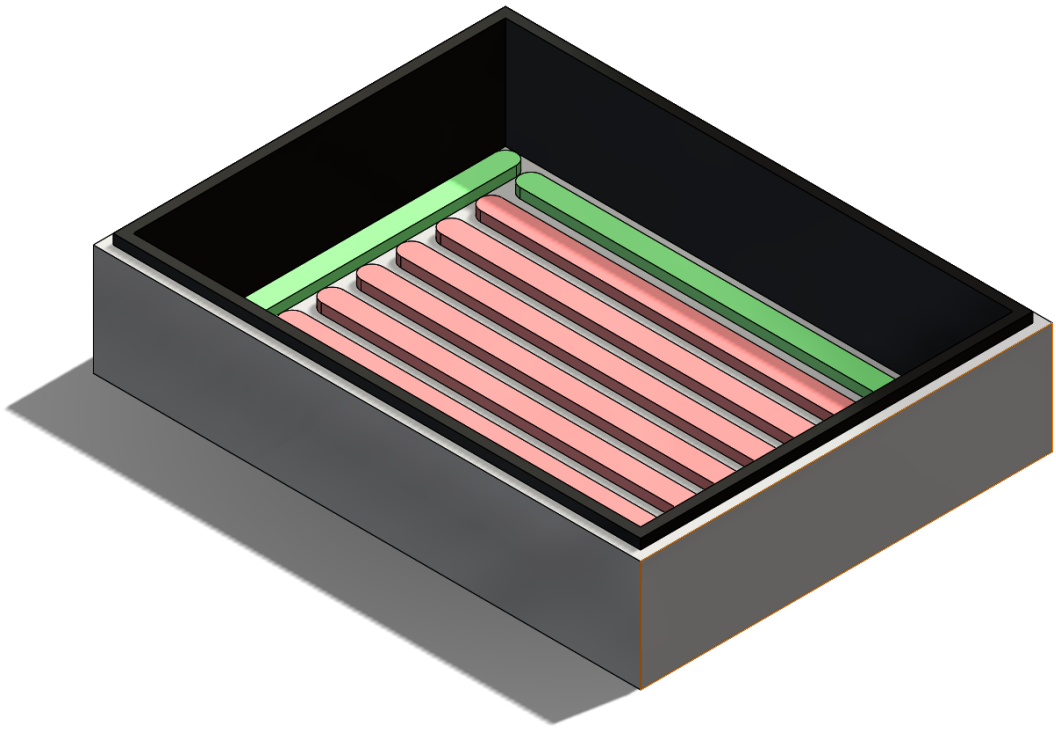


Figure 1: A SolidWorks sketch of the Magnet-Induced Levitation Device. Red magnets denote a repulsive force while green magnets represent an attractive force. The raised black interior is the foam layer that surrounds the horizontal translation prevention track.

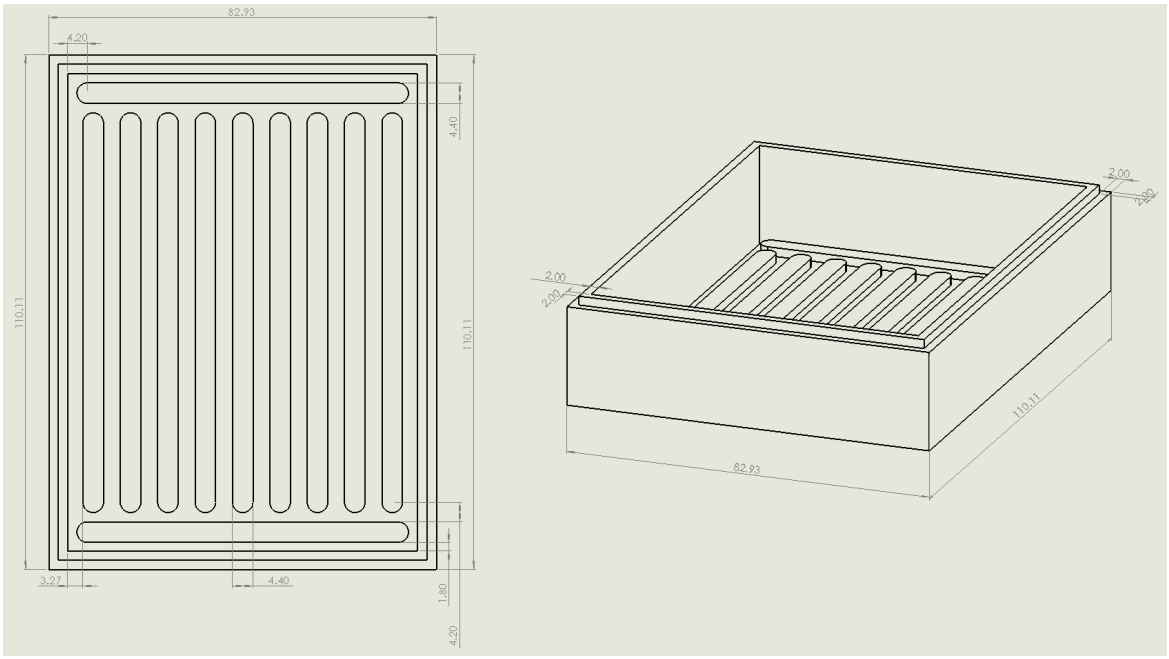


Figure 2: A SolidWorks drawing of the Magnet-Induced Levitation Design. The left side shows a top view and the right shows a dimetric side view. All dimensions are in cm.

As can be seen in Fig. 2, the device utilizes strips of magnets of both polarities, with repelling forces (denoted with red in Fig. 1) in the center and attracting forces (denoted with green in Fig. 1**)** along the edges. The repelling magnets create the cushion while the attracting magnets stabilize the device and ensure that if the ambulance encounters any large bumps (railroad tracks, for example), the incubator will not be excessively displaced vertically. Horizontal translation of the incubator is inhibited by the placement of a foam-coated track around the sides of the incubator. The 2 cm thick foam layer would ideally eliminate vibrations produced by slight horizontal displacement.

Metal and Gel Composite Damper

The second design considered was a damper consisting of metal and gel concentric layers. The design is L-shaped and would attach to the corners of the incubator's inner tray with ball-and-socket joints, as shown in Fig. 3. This will convert the incubator's vibration of the inner tray into a gentle rocking motion. A close-up view of this joint system can be seen in Fig. 4**.**

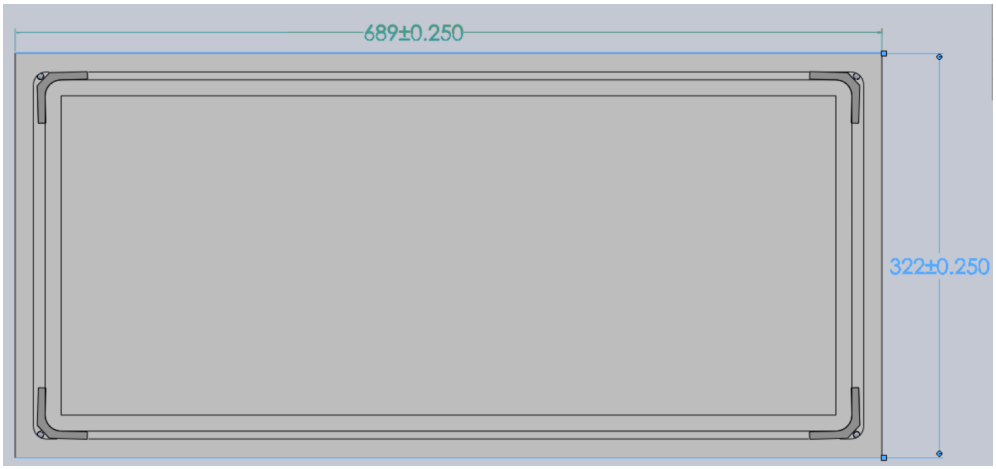


Figure 3: A SolidWorks sketch of the Metal and Gel Composite Damper from the top plane. All dimensions are in mm.

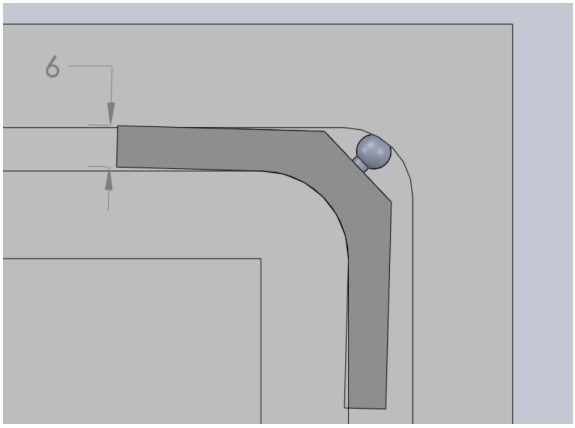


Figure 4: A close-up view of the ball-and-socket joint that connects the damper system to the outer tray of the incubator. All dimensions are in mm.

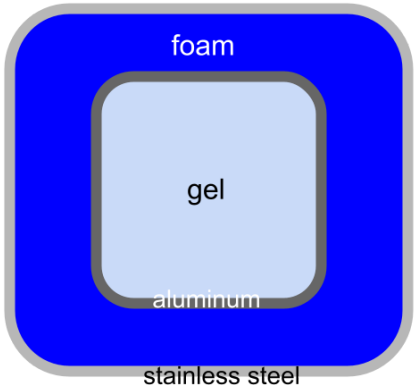


Figure 5: A labeled cross-sectional view of the concentric four-layered damper system.

The damper consists of four concentric layers, which can be visualized in Fig. 5. The innermost is a silicone gel, which is wrapped in a thinner layer of aluminum. The third layer is a thicker coating of foam, which is encased in a thin layer of stainless steel, forming a medical-grade exterior that is easy to sterilize. This design was inspired by the work of Biju et. al, who utilized the natural vibration reduction properties of woodpecker anatomy. Dampening curves from Biju et. al showed promising results for vibration reduction of this composite material, which can be seen in Fig. 6 [18]. Application of this damper for vibrations in an incubator has the potential to be immensely successful.

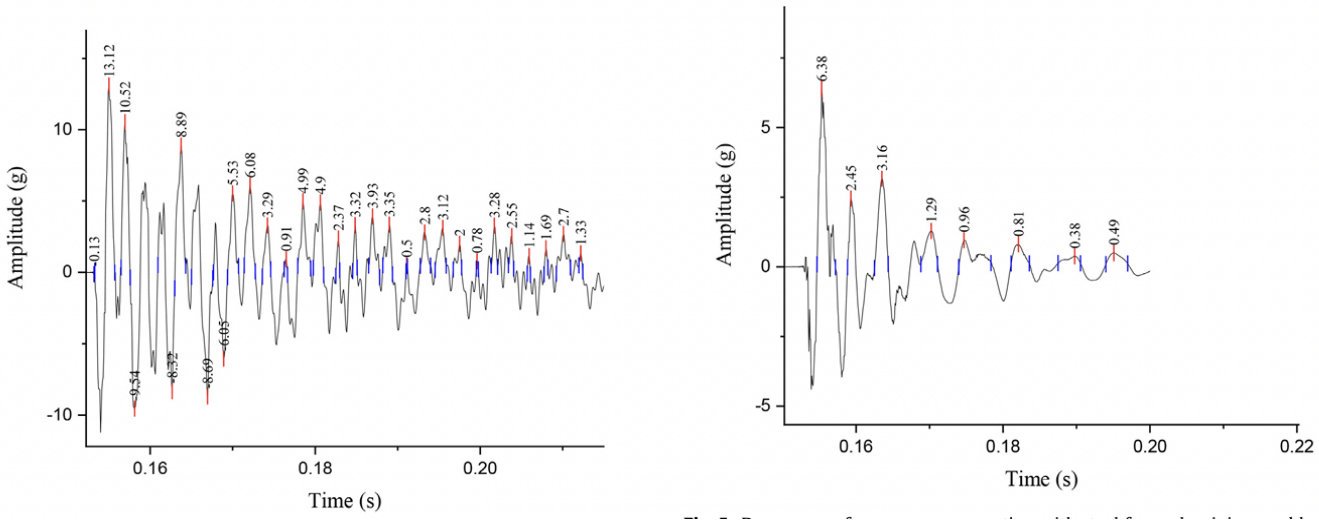


Figure 6: Damping curves for solid stainless steel (left) and the composite damper (right).

Shock-Absorbing Mat System

The third and final design that was evaluated was a shock-absorbing mat system. This simple yet elegant solution places a dampening foam mat between the incubator and the stretcher. The mat is to be half an inch thick and have properties similar to the flooring of a weightlifting gym, as shown in Fig. 7.

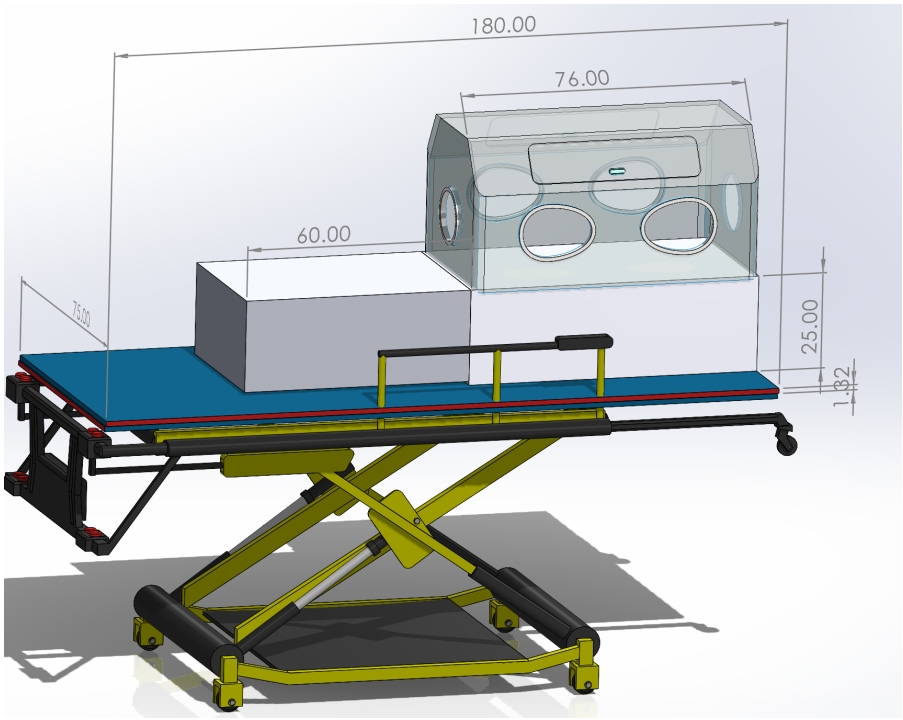


Figure 7: The entire incubator setup with the addition of the shock-absorbing mat system, which is shown in blue. All dimensions are in centimeters.

As of now, the standard stretcher and incubator setup only has padded areas where there is direct contact with the patient. A layer of high-density foam between the heavy incubator and the stretcher would ideally reduce the resonance of vibrations caused by hard metal and plastic components bumping into each other: thereby reducing whole body vibrations for the neonate during transport.

IV. Preliminary Design Evaluation

Design Matrix

In order to adjudicate which design would be the most effective, the team constructed a design matrix based on the most important considerations in the product design specifications, which are fully outlined in Appendix A. Seven criteria were considered in the evaluation of the designs: safety, projected performance, compatibility, ease of fabrication, longevity, and cost. The results of this weighted analysis can be seen in Table 1.

The most highly weighted criteria was safety due to the high-intensity environment of the ambulance. The safety category assesses the potential for the device to cause harm or damage during both storage and use. Any mechanical, electrical, or chemical elements of the device must be hazard-free and easy to clean and sanitize for continuous use.

The projected performance category assesses a device's ability to effectively reduce whole-body vibrations in neonates. The target is WBV reduction below 0.87 m/s^2 as recommended by the American Conference of Governmental Industrial Hygienists [9]. This category was given a weight of 25 because it is an evaluation of a prototype's ability to reduce whole body vibrations. Any device that does not meet the performance requirements pose the risk of causing additional harm to the neonate.

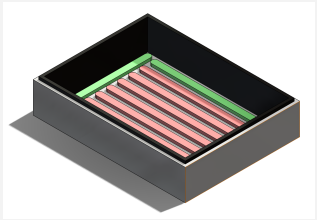
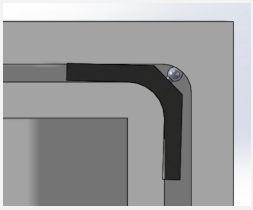
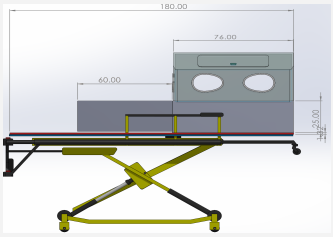
The compatibility score predicts the device's ability to function without negatively impacting the travel incubator or any of the other equipment associated with the transport unit. Compatibility is a higher ranked category at 20 because the device should be easily integrable into the existing transport incubator setup; however, this is a secondary concern in comparison to safety and projected performance. Ideally, any potential designs would not require any significant modification to the existing transport system.

Ease of fabrication is defined in this context as the level of difficulty to create a working prototype of the design within the constraints of accessible materials, machinery, and time this semester. Although the focus of this category is on small scale preliminary fabrication, the complexity of manufacturing on a larger scale could be factored into evaluation in this category as well. This category was given a weight of 15 because feasibility is an important consideration to ensure a testable prototype can be created; however, producing a device that effectively minimizes whole body vibrations is the ultimate goal and performance should be prioritized over simplicity.

The longevity category assesses the duration of the device's life in service. Since the frequency of neonatal transports at UW Hospitals is unpredictable, it is important that the device can be either stored for long periods without use or used continuously for many hours at a time. Although it is important for the device to last for many years, its rating was among the lowest since the projected performance of the device would determine whether the device provides a significant impact to justify replacing it over any period of time.

The cost category was scored based on the expenses of the materials as well as the cost to make the final product. As mentioned in the product design specifications, all expenses of prototyping should remain under $500. The score for this criteria is less important to the client compared to safety and projected performance, and has mentioned that if the design were to be worth it, the $500 budget has some flexibility.

Table 1: A design matrix comparing the three designs.

Design Categories (Weight)	**Magnet-Induced Levitation** 		**Metal/Gel Composite Damper** 		**Shock-Absorbing Mat(s)** 	
Safety (25)	3/5	15	4/5	20	5/5	25
Projected Performance (25)	3/5	15	5/5	25	2/5	10
Compatibility (20)	2/5	8	3/5	12	4/5	16
Ease of Fabrication (15)	1/5	3	2/5	6	5/5	15
Longevity (10)	3/5	6	3/5	6	4/5	8
Cost (5)	4/5	4	3/5	3	3/5	3
Total Points:	51		72		67	

Design Evaluations

In evaluating the Magnet-Induced Levitation Device, it received a score of ⅗ in both safety and projected performance. The main safety concern was the potential for the repulsive force to excessively displace the incubator and create more forces that the neonate would

experience. It was deducted in the projected performance category due to the precision required to fabricate an effective device and for how finicky the magnets might be even after the device has been fully fabricated. The compatibility score was a ⅖ since hospital equipment and copious amounts of magnetic field are relatively incompatible. This device would be the most difficult to fabricate due to the need for the magnets to be exactly properly placed. This is reflected in its score of ⅕ in the ease of fabrication category. Since magnets weaken over time, the device scored ⅗ with regard to longevity. The cost score was ⅘ due to the fact that magnets can be relatively inexpensive. Based on the scores assigned in the design matrix, this design scored an overall 51 out of 100 available points. Even though this design is unique and creative, there are multiple significant barriers to the safe and successful fabrication and implementation of this design.

Evaluating the Magnet and Gel Composite Damper resulted in a safety score of ⅘. Close proximity to the neonate was the source of the deduction in an otherwise relatively safe design. 5/5 points were awarded in the projected performance category due to the promising results of this composite's damping curve shown in Fig. 6**.** The compatibility score for this design was a ⅗ due to the fact that it would take up space inside the incubator, which is extremely limited. Flight nurses, EMTs, and doctors that the team has consulted with have gone as far as saying modifying anything inside the incubator might be a non-starter. Fabricating this device will be challenging due to the need to ensure proper thicknesses of all materials on such a small scale. This awarded the design a ⅖ in the ease of fabrication category. The ⅗ in the longevity category was the result of concerns over the durability of the ball-and-socket joints under repeated and frequent use. Since all materials must be medical grade, this drives up the projected price and resulted in a ⅗ cost score. Overall, this design scored a 72 on the design matrix. This design takes into consideration the effectiveness of dampers in absorbing shock as well as the limited amount of space within the incubator to intervene with any kind of accessory.

The Shock-Absorbing Mat System was determined to be the most safe design, scoring a 5/5. This is due to the placement of the mats on the stretcher itself, far away from possible contact with the neonate. It scored less well in the projected performance category due to the fact that the amount of vibrations that can be absorbed is limited to the thickness of the foam material. Only having half an inch of mat results in the deduction to a ⅖ score. As for compatibility, the device scored a ⅘ since the only impedance to the equipment's normal function is the chance of a slight lean from its now less rigid base. This, however, is unlikely to have a

significant impact. A 5/5 in the ease of fabrication category was awarded due to the relative simplicity of the design, simply requiring the mats to be cut to the right dimensions. The device scored a ⅘ in longevity due to the durable but not indestructible nature of high-density foam mats. Assessment of costs required resulted in a score of ⅗ since a quality mat that would have all the characteristics the team is looking for would cost hundreds of dollars. Overall, the shock-absorbing mat design scored a 67 on the design matrix, placing it second on the team's evaluation list. The design scored well in several areas due its simplistic design and readily available materials. However, the predicted effectiveness and the cost of the materials revealed that this design may not be the most practical. It is possible that this design idea could be used in conjunction with another design and that the interaction between multiple vibration reducing designs could allow for the best possible solution to the problem at hand.

Proposed Final Design

After careful consideration of the factors in the design matrix and further research, the team has decided to combine elements from multiple designs in creating the final prototype. This design will consist of both a metal and gel composite damper as well as a shock-absorbing mat system. Both designs are intended to operate in completely different parts of the incubator, so combining them will be relatively straightforward. Stability of the neonate will be further insured by the implementation of a head restraint system as opposed to the standard five-point harness. This system for securing the neonate has been shown to more effectively mitigate whole-body vibration than the five-point harness that most hospitals currently implement [4]. Together, these three components will work to stabilize the neonate by reducing vibrations at three distinct points.

V. Fabrication/Development Process

Materials

The device consists of four concentric layers of shock-absorbing material, and a pin joint used to secure the device to the incubator tray. The innermost layer is a silicone gel, followed by

an aluminum layer, foam layer, and an outer stainless steel layer. A materials and cost list to fabricate the Metal/gel Composite Damper can be found in Appendix B.

The innermost layer is a sheet of silicone that is 0.060 inches thick. This layer has a durometer value of 40, which is about the hardness level of a gel shoe insert. As the innermost layer, this silicone will be absorbing residual shock left unabsorbed by the outer layers, and attempts to mimic a woodpecker's cerebrospinal fluid. The relative softness of this layer allows for this absorption. A sheet of this thickness was used due to the size constraints of the device. The device must fit within the 6 mm space between the inner and outer trays of the incubator.

The silicone layer is followed by a coating of aluminum foil. Once again due to size constraints, aluminum foil is the thinnest option to coat the silicone sheet with. In addition, this foil can be layered to further increase its shock absorption capabilities. Aluminum foil is also very inexpensive to purchase.

A sheet of foam surrounds the aluminum foil layer. This foam sheet is 0.125 inches thick. This foam was used as an initial shock absorbing layer. The foam will act as a first line of defense in damping the vibrations of transport, and mimics the characteristics of a woodpecker's spongy bone.

The final outermost layer of the device is a stainless steel tube, which encases all of the aforementioned layers. The open faces of the tube will be The tube is 0.5 inches tall, with walls 0.065 inches thick. Stainless steel was chosen because it is hard enough to withstand the wear and tear we anticipate for the device, and can also be sterilized easily.

To fasten the layered shock absorber to the incubator tray, a coiled spring pin is used. These pins are easy to remove and place, and their coiled nature allows for adaptability in shape in response to shock and vibration. The pin is placed into a hole drilled into the device on one side, and the other side is placed in a cap nut, which fits into the corner of the incubator tray. A cap nut is used because of its rounded shape, which mirrors the form of the incubator tray corner.

Methods

After obtaining the materials detailed above, the silicone sheet will be measured and cut to fit within the stainless tube. The silicone, once the appropriate size, will be coated in a continuous layer of aluminum foil. The foil will be cut, folded over the foam, smoothed over, and adhered to the gel using a thin layer of spray adhesive on the silicone sheet. Then, four

pieces of foam will be cut to match the dimensions of each of the faces of the aluminum-coated silicone piece. Each foam piece will then be adhered to the aluminum foil-coated silicone sheet using a spray adhesive. Then, the spray adhesive can be used to adhere the foam-coated piece to the inner walls of the stainless steel tube. This process will be replicated twice, to construct a total of two stainless steel tubes with the layers inside.

The tubes will then be arranged in an L shape and welded together. Stainless steel sheets will be welded over each exposed face of the tubes to fully enclose the layered material. A hole will be drilled into the corner of the L-shaped layered material. One end of the coiled spring pin will be inserted into a cap nut, and the other end will be inserted into the hole in the layered material. Step-by-step instructions to fabricate the final design can be found in Appendix C.

Final Prototype

The materials listed in Appendix B and the fabrication protocol described in Appendix C are currently being developed and organized so that a final prototype will be created within the next four weeks. This will allow the team enough time to continue into the testing phase and conclude whether the product has met the specifications described in Appendix A.

Testing

The team aims to measure the strength of the vibrational waves in the resting area of the neonate within the incubator, the floor of the transport vehicle, and the deck of the transport unit as a measure of the Power Spectral Density. The PSD is a measure of the mean square acceleration per unit of bandwidth and can be used to evaluate the randomized vibrations that occur during transport [19]. The shape of a Power Spectral Density plot can be used to define the mean acceleration of a random signal at any frequency. The area under the plotted PSD curve is the mean square (g^2) of the signal and the square root of the graphed area is the acceleration's overall root-mean-square (RMS) value (σ) [4], [20].

Data collection will be completed using the accelerometer built into each team member's phones. The "Gauges" application is free to download from the Apple App Store and can measure acceleration in the x, y, and z directions. The app will also remember the maximum and minimum values for a period of time which will be necessary for the calculations of the PSD

curve. Since there will be at least 6 devices –one from each team member– that can record measurements, the devices will be placed strategically in order to cover the greatest area for the generalization of a PSD value for a given space. The team will place two devices at either the head and foot area of the incubator, two more at the top and bottom of the stretcher deck, and two more devices at the front and back of the transport bay.

In order to collect data and gain access to the transport vehicle, the team will work with the client to schedule a convenient time to travel in the ambulance with the neonatal transport unit. The team should plan to travel in the ambulance for 20-30 minutes and should direct the ambulance driver to drive at normal transport speeds and across a variety of obstacles and road conditions in order to evaluate a large set of random vibrations. The team will collect data with and without the Metal/Gel Dampers placed in the transport unit so that an evaluation of the statistical significance of including the proposed solution can be determined.

The primary test that a successful prototype must pass is to reduce the vibrations and mechanical forces felt by the neonate since whole-body vibration levels during transport can exceed the recommended 0.87 m/s^2 in adults as mentioned in Appendix A [9]. An analysis of the PSD curve will allow the team to determine whether the whole body vibrations have been successfully reduced to be below 0.87 m/s^2. If this test is passed, a proof of concept has been established and the team can move forward on addressing other components of the Product Design Specifications such as the size and weight of the prototype.

VI. Results

There are no testing results available at this time, as the group is still in the process of creating a working prototype.

VII. Discussion

The proposed final design: the metal and gel composite damper, will be refined, fabricated and tested to evaluate the effectiveness of the device at reducing vibration experienced by the neonate. Further research after evaluation of the designs via the design matrix introduced additions and modifications that could elevate the efficacy of the device at reducing vibration.

The metal/gel composite damper features a ball and socket joint aimed at reducing vibration by diverting vibrational forces into movement of the joint rather than directly into the neonate. The degrees of freedom allowed by the ball and socket joint were not set in the preliminary design, however a vibration damping universal joint developed by Ford Motor Company for use in a gear shift rod had a high efficacy at reducing vibration with three degrees of freedom. Their testing concluded that this level of freedom limited rotational deflection of components attached to the joint to the greatest extent [21]. Although in a different context, these mechanistic principles could be applied to the ball and socket component of the design. In fabrication of the ball and socket joint, precision will be necessary to guarantee that the joint fits exactly in the space between the damper and the outer tray. If the joint has too little space, it will be unable to rotate effectively, eliminating its vibration reducing capabilities. The second vibration-reducing component of the design was the damper which featured four concentric layers of different materials. The study that this component was based upon measured vibration amplitude of the cross section for a set-up with four concentric layers: steel, foam, aluminum, and silicone gel, as well as additional configurations [18]. These values were then used to calculate a damping ratio. The four material specimen had the highest damping ratio with a value of 0.0382, and a prism with aluminum and silicon layers had the second highest with a value of 0.0331. There is some concern about the feasibility of fabricating all four layers in the dimensions required by the space between the inner and outer trays of the isolette. The team plans to proceed with four layers, but there is evidence that a damper with two layers of aluminum and silicone gel could be nearly as effective if fabrication constraints necessitated a reduction in the number of layers.

In addition to fabrication, several ethical considerations were taken into consideration in the development of the design, with safety and accessibility as central priorities. The use of steel as the outer layer of both the damper, and ball and socket joint of the design ensures that the device meets all biosafety requirements for medical devices, as it can be easily removed and sterilized using an autoclave or ethylene oxide [22]. The device does not include any electrical components and is not touching or in close proximity to the neonate, reducing safety risks that could be posed in the event that the device malfunctions. Although the current design is based around the dimensions of the International Biomedical Voyager transport isolette, the concept

could work in any standard neonatal transport system that utilizes an inner and outer tray by modifying the dimensions of the damper.

Beyond the modifications and considerations related to the metal and gel composite damper, the team has also evaluated the addition of a head restraint and the incorporation of the shock-absorbing mat into a system that would reduce vibration via a multi-faceted approach. The current standard restraint system in the isolette features a five-point harness with straps across the shoulder, hips, and legs. A study conducted at Carleton University investigated the vibration levels experienced by neonates in the use of the standard harness and a proposed head restraint system [4]. The head restraint system included straps across the forehead and torso with lateral supports on either side of the head. In the study, this system was proven to reduce vibrations experienced by the neonate by 1.7-3.3 times in comparison to the standard system. This set-up could be added as an accessory to the design and extend reduction of vibration by stabilizing the patient directly. The shock-absorbing mat, as described in the preliminary designs section, would require little modification of the existing system and could reduce the magnitude of the vibrational force experienced by the metal and gel composite damper, increasing effectiveness of the system overall. All three elements will be implemented into the existing transport set-up with the goal of mitigating vibrational forces through stabilization and diversion of forces applied by the floor during movement.

VIII. Conclusions

Transporting a critically-ill neonate to a Neonatal Intensive Care Unit (NICU) is likely to reduce their chances of survival compared to those that do not require transport. The goal is to reduce vibrations during transport to increase the chances of survival for those transported between hospitals. The chosen design of the metal and gel composite damper uses a multilayered material with concentric layers of silicone gel, aluminum, foam, and stainless steel. The devices would sit in the corners in between the inner and outer trays inside the incubator. In the future, in conjunction with the metal and gel damper design the foam padding will also be implemented and will be placed underneath the incubator monitoring box but above the sled. The addition of a head and torso restraint could also benefit the neonate. The proposed head restraint would have a

strap across the top of the head and lateral boundaries to stabilize neck position, and another strap around the torso of the neonate.

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X. **Appendix**

Appendix A: Product Design Specifications

Product Design Specifications: Neonatal Transport Unit

September 23, 2022

BME 300/200

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Team Members:

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Function:

Critically ill neonates as a result of birth defects or other disorders require transport to neonatal intensive care units (NICU). The quality of that transport heavily influences survival or morbidity [1]. Transport in ambulances or helicopters, while necessary, induces physiological stressors including vibration, translational inertia forces, and rotational inertia moments [2]. These environmental exposures are associated with intraventricular hemorrhage (IVH) in transferred neonates, leading to subsequent neurodevelopmental impairment or death [3]. The current transport incubator has ventilators, monitoring equipment, and temperature control mechanisms, but no control of the physical stressors aforementioned. The natural frequencies of the incubator (12-16 Hz) accentuates the ambulance's natural frequencies (2.5-15 Hz), resulting in amplified vibration felt by the neonate [4]. The proposed device will oppose the mechanical forces transmitted through the transport vehicle or undergo purposeful motion which acts to absorb such forces. The device will improve neonatal transport outcomes by mitigating the effects of vibration and motion, improving the safety of the critical neonate, and simplifying the required care by the medical transport team.

Client Requirements:

1. The device must minimize vibrational forces such that a critical neonate does not sustain injury.
2. The device must minimize translational and rotational forces enough to prevent injury to critical neonates.
3. The device must mitigate sound levels experienced by the neonate in order to eliminate stress and injury (maximum accepted level of 45 dB) [5].
4. The device must either attach to current incubators or include all the associated functions including ventilators, monitoring equipment, and temperature control mechanisms.
5. The device must be small enough to fit within a standard ambulance and allow the movement of the transport team.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements:

- The product must decrease the amount of whole-body vibrations to be below 0.87 m/s^2 as recommended by the ACGIH for the exposure of adults [2].
- The product should be capable of reducing the volume of excessive sound levels to be below 45 decibels in order to prevent permanent hearing damage while riding in the transport vehicle [6] .
- The product should allow the infant to maintain proper vital signs in a range appropriate for its size, age, and condition:
    - A heart rate between 100 and 160 beats per minute [7].
    - A respiratory rate between 30 and 60 breaths per minute [7].
    - Blood pressure of no less than 30mmHg systolic [8].
    - An oxygen saturation level between 85 and 95% [9].

b. Safety:

- The transport bed must allow for continuous treatment and should not disrupt the incubator, mechanical ventilator, or monitoring equipment.
- The device should be sterilizable and resistant to degradation that can be caused by common sterilization chemicals such as ethylene oxide [10].
- The device must not have any sharp edges or long cords that the neonate could interact with.

c. Accuracy and Reliability:

- The device should require no maintenance during its lifetime, but should be easy to remove or replace if any malfunctions occur.
- The device should be functional for neonates ranging from 0.66 to 12 pounds [11].

d. Life in Service:

- The service life of a device should allow for 5,000 lifetime transports, or an estimated 5 years of operation, assuming that all ideal practices and operating conditions are followed.

e. Shelf Life:

- The device should last for a minimum of 7 years if any electrical components are involved in the design or a minimum of 12 years if no electrical components are included [12].

f. Operating Environment:

- The operating environment of the device will be ground transport using an ambulance with an incubator [13].

g. Ergonomics:

- The device should have a simple screen interface to control any electrical components.
- The entire device will be designed such that it causes no interference to ambulance personnel when installed and functional.

h. Size:

- The device should be able to fit inside the Voyager transport incubator by International Biomedical, which has dimensions of 53cm H x 48cm W x 99cm L [14].
    - The device could also be created to fit inside the ambulance under the incubator.

i. Weight:

- The device should be no more than 10lb which is equivalent to 5% of the incubator's weight when empty [15].

k. Materials:

- The materials should be safe to use in a medical environment and be in compliance with all federal EMS regulations. [13].

l. Aesthetics, Appearance, and Finish:

- The device should be entirely white or gray to make it easy to identify when cleaning is required [16].

- The device should be distinguishable enough from the incubator that it is not a challenge to locate and remove.
- Aesthetics should not impede the functionality of the device.

2. Product Characteristics:

a. Quantity:

- One functional prototype should be developed by the end of the semester.
- Once refined, the prototype will be mass produced for the general market.

b. Target Product Cost:

- The device will cost no more than $500 to fabricate and test.

3. Miscellaneous:

a. Standards and Specifications :

- The device must be compatible with a sterilization process in accordance with ISO 14937 [17].
- The product will be a Class II medical device according to FDA standards due to moving components that pose some risk to the patient and measurement capabilities [18].
    - FDA approval will be required for commercial use of the device.
- The device must comply with ISO 2631 which sets acceptable frequencies of whole body vibration, established to minimize health risk and discomfort [19].
    - Specifies that for health and comfort, vibrations should not exceed 0.5-80Hz.
    - Specifies that for patients that are motion sick, vibrations should not exceed 0.1-0.5Hz.
- IEC 60601-2-20 sets standards for the basic safety and essential performance of neonatal transport incubators [20]. This standard has been recognized by the FDA under Sec. 880.5410.

b. Customer:

- The target customer for our product is a hospital; specifically, the department within the hospital that manages neonatal transport and/or a Neonatal Intensive Care Unit (NICU).

- The device should be easily compatible with the equipment already used by the hospital, including incubators, transport carts, ambulances, and any accessory equipment used to treat patients during transport.

c. Patient-Related Concerns:

- The device should not pose additional risks to the patient during transport.
- Thorough testing must be completed to ensure the device does not decrease comfortability for the patient.

d. Competition:

- One category of competing designs involves the use of passive vibration isolation systems such as the use of a quasi-zero-stiffness (QZS) isolator placed beneath the infant compartment. This design has a high ability to attenuate low frequency vibrations [21].
- Magnetorheological (MR) dampers address variations in the international roughness index and the curve radius of roads in order to reduce vibrations within the vehicle. The pneumatic suspension system can be toggled between a compliant and stiff setting while the MR damper has an adjustable continuous range of viscosities that allow it to work in tandem with the pneumatic suspensions to reduce vibrations [22].
- A plate mounted to the incubator and another to the stretcher with a gap in between. Between the parallel plates springs are attached, “preferably gas springs, with a range and a damping effect” [23]. The spring reduces vibrations transmitted to the infant during transport.

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Appendix B: Materials and Costs

Material	Specs	Vendor	Quantity	Cost
General Purpose 304 Stainless Steel Rectangular Tube	0.065 in wall thickness, 0.5 in outside height, welded, 36 in total length	Grainger	1	$22.80
General Purpose 304 Stainless Steel Sheet	0.057 in thickness, 12 in x 12 in sheet	Grainger	1	$64.99
Vibration-Damping Pad for Heavy Machinery	0.125 in thickness, 12 in x 12 in sheet	McMaster-Carr	1	$51.24
Reynolds Wrap Heavy Duty Aluminum Foil		Target	1	$6.29
Matte Non-Reinforced Silicone Sheeting	0.060 in thickness, 12 in x 12 in sheet	Specialty Manufacturing Inc	1	$26.00
Stainless Steel Coiled Spring Pin	1/4 in diameter, 3/4 in fastener length	Grainger	1 set of 10	$22.32
Cap Nut	1/4 in thread size, zinc plated	Grainger	1 set of 25	$14.64
3M Series 27 Spray Adhesive	16 fl oz	Grainger	1	$13.68
			Total cost:	**$221.96**

Appendix C: Fabrication Methods

After obtaining the materials detailed above, the silicone sheet was measured and cut to fit within the stainless tube. The silicone, once the appropriate size, was then coated in a continuous layer of aluminum foil. The foil was cut, folded over the foam, smoothed over, and adhered to the gel using a thin layer of spray adhesive on the silicone sheet. Then, four pieces of foam were cut to match the dimensions of each of the faces of the aluminum-coated silicone piece. Each foam piece was then adhered to the aluminum foil-coated silicone sheet using a spray adhesive. Then, the spray adhesive was used to adhere the foam-coated piece to the inner walls of the stainless steel tube. This process was followed twice, to construct a total of two stainless steel tubes with the layers inside.

The tubes were then arranged in an L shape and welded together. Stainless steel sheets were welded over each exposed face of the tubes to fully enclose the layered material.

A hole was drilled into the corner of the L-shaped layered material. One end of the coiled spring pin was inserted into a cap nut, and the other end was inserted into the hole in the layered material.

1. Cut aluminum two stainless steel tubes to 1.2 inches in length.
2. Measure and cut a silicone sheet to 0.12 in x 0.12 in x 1.2 in
3. Measure and cut a large sheet of aluminum foil
4. Apply a thin layer of spray adhesive to silicone sheet on one face.
5. Smooth over aluminum foil on the face that was sprayed with adhesive.
6. Apply a thin layer of spray adhesive to the silicone sheet on an adjacent face.
7. Fold and smooth over aluminum foil on the face that was sprayed with adhesive.
8. Repeat steps 7 and 8 until every face of the silicone sheet is covered in aluminum foil. Cut excess foil.
9. Cut four pieces of foam to 0.125 in x 0.37 in x 1.2 in, and two pieces of foam to 0.37 in x 0.37 in x 0.125 in.
10. Spray aluminum foil with adhesive on one face.
11. Press corresponding shaped foam on to sprayed aluminum foil.
12. Repeat steps 11 and 12 until every face is covered with foam.
13. Spray inner walls of stainless steel tube with adhesive.

14. Insert foam-coated layered material into a stainless steel tube.
15. Repeat steps 3 through 15 for the other stainless steel tube.
16. Line up the tubes in an L shape and weld together.
17. Cut two stainless steel sheets to <dimensions>.
18. Weld stainless steel sheets to exposed faces of layered material.
19. Drill ¼ inch hole into outside corner of L shape.
20. Insert coiled spring pin into drilled hole.
21. Insert coiled spring pin into cap nut.
22. Repeat steps 2 through 22 three more times to make a total of four corner dampers.